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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/519,044 | 09/02/2005 | Robert Norman Barker | 0380-P03549US0 | 6955 |

110 7590 11/30/2007
DANN, DORFMAN, HERRELL & SKILLMAN
1601 MARKET STREET
SUITE 2400
PHILADELPHIA, PA 19103-2307

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| EXAMINER |
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JUEDES, AMY E

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| ART UNIT | PAPER NUMBER |
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1644

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| MAIL DATE | DELIVERY MODE |
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11/30/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/519,044

Applicant(s)

BARKER ET AL.

Examiner

Amy E. Juedes, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 September 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-40 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-40 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

1. Restriction is required under 35 U.S.C. 121 and 372.
2. This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.
3. In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Claims 1 link(s) inventions 1-4. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s) 1. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Group 1, claims 2-5 and 7, drawn to a method for tolerizing a population of cells comprising contacting a population of cells with a toleragenic peptide in vitro.

Group 2, claims 2-5 and 7, drawn to a method for tolerizing a population of cells comprising contacting a population of cells with a nucleic acid encoding a toleragenic peptide in vitro.

Group 3, claims 2 and 6-7, drawn to a method for tolerizing a population of cells comprising administering a toleragenic peptide to a subject.

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Group 4, claims 2 and 6-7, drawn to a method for tolerizing a population of cells comprising administering a nucleic acid encoding a toleragenic peptide.

Group 5, claims 8-13 and 40, drawn to a composition comprising EBV LMP1 or LMP2, or a toleragenic peptide thereof.

Group 6, claims 8-13, drawn to a composition comprising a nucleic acid encoding EBV LMP1 or LMP2, or a toleragenic peptide thereof.

Group 7, claims 15-25, drawn to a method for assessing the tolerogenicity of a test peptide comprising contacting a cell population with a test peptide and determining IL-10 expression.

Group 8, claims 26-33, drawn to a method for assessing the tolerogenicity of a test peptide comprising contacting a cell population with a test peptide and a target antigen, and assessing cell proliferation or expression of IL-4, IL-2, IL-12 or IFN-gamma.

Group 9, claims 34-39, drawn to a method for assessing the tolerogenicity of a test peptide comprising contacting a first cell population with a test peptide and second cell population with a control peptide.

4. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

5. The species are as follows:

Irrespective of the group elected, Applicant is required to elect a specific peptide or nucleic acid encoding a peptide, such as one of those listed in claim 1, 13, or 40, as appropriate.

and list all claims readable thereon including those subsequently added.

6. Applicant is advised that a reply to this requirement must include an identification of the species that is elected

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consonant with this requirement. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

7. The inventions listed as Groups 1-9 and the species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reason:

The invention of Group 5, the composition comprising LMP1, has no special technical feature that defined the contribution over the prior art of Izumi et al., 1997.

Izumi et al. teach a composition comprising LMP1 (see page 1448, in particular). Izumi et al. further teach said LMP1 linked to FLAG (i.e. a target antigen). Furthermore, since the specification discloses that P1 to P75 peptides are fragments of LMP1, said LMP1 taught by Izumi et al. inherently comprises the peptide sequence of P1-P75.

8. Since Applicant's inventions do not contribute a special technical feature when viewed over the prior art they do not have a single general inventive concept and so lack unity of invention.

9. Accordingly, Groups 1-9 are not so linked as to form a single general inventive concept and restriction is proper.

10. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

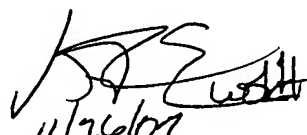
11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy E. Juedes, Ph.D. whose telephone number is 571-272-4471. The examiner can normally be reached on 8am - 5pm, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Amy Juedes, Ph.D.
Patent Examiner
Technology Center 1600


11/26/07
G.R. EWOLDT, PH.D.
PRIMARY EXAMINER